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10/783,648

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Geoffrey N. Holland

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EXAMINER

RINES, ROBERT D

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,648	Applicant(s) HOLLAND ET AL.	
	Examiner R. David RINES	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 2 January 2009. It is noted that this application benefits from Provisional Patent Application Serial Nos. 60/509,404 and 60/527,583 filed 10/7/08 and 12/5/08, respectively. Claims 17-20 have been added. Claims 1-20 are pending.

Rejections of claims 1-16 are maintained as set forth in the previous Office Action mailed 1 July 2008, herein incorporated by reference. Applicant's newly added claims 17-20 are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[2] Claims 1-2, 4-12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (United States Patent Application Publication #2006/0106649).

As per claim 1, Eggers et al. disclose method for downloading a drug library from a medication management unit to a medical infusion device having a primary memory and an existing drug library stored in the primary memory, comprising: determining that a drug library update needed event has occurred (Eggers et al.; paragraphs [0034] [0036] [0057] [0063] *see change location and new library); transmitting a new drug library from the medication management unit to the medical infusion device upon occurrence of the drug library update needed event (Eggers et al.; paragraphs [0034] [0057] *see location specific configuration database); storing the new drug library in a memory of the medical infusion device while maintaining the existing drug library in the primary memory (Eggers et al.; paragraphs [0057] [0070]); determining that a specific trigger

event has occurred (Eggers et al.; paragraphs [0034] [0057]); and replacing the existing drug library in the primary memory with the new drug library upon occurrence of the trigger event (Eggers; paragraphs [0034] [0057]).

While Eggers et al. disclose storing the configuration and associated drug libraries in the memory of the infusion pump, Eggers et al. fail to specify storage in a cache memory. However, Examiner submits that it would have been obvious to use of the cache memory to store the drug library prior to storage in the bulk memory with the motivation of employing a well-known computer memory structure to facilitate a transfer of data.

As per claim 2, Eggers et al. disclose a method wherein the trigger event is selected from the group consisting of a completed infusion, a stopped infusion, a determination that the device is in a configurable mode, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library NOTE: The selection of additional trigger events to constitute a user choice that is accommodated by the Eggers disclosure).

As per claim 4, Eggers et al. disclose a method wherein the drug library update needed event is selected from the group consisting of a completed infusion, a stopped infusion, elapsed time, a

specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library.).

As per claim 5, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medication management unit (Eggers et al.; paragraphs [0034] [0056] [0057] [0063] *see patient specific parameters).

As per claim 6, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medical device (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

As per claim 7, Eggers et al. disclose a method wherein the step of determining when the drug library update needed event has occurred is done by the medication management unit (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

As per claim 8, Eggers et al. disclose a method wherein the step of determining when the drug library update needed event has occurred is done by the medical device (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

NOTE: regarding claims 5-8, Examiner interprets the applied teachings of Eggers et al. to indicate that the type of trigger event dictates which networked device initiates the configuration change.

As per claim 9, Eggers et al. disclose a method further comprising the step of performing an infusion with the medical device using the existing drug library during the transmitting step (Eggers et al.; paragraphs [0034] [0051] [0057]).

As per claim 10, Eggers et al. disclose a method wherein the new drug library is stored in the cache memory while the medical device is performing an infusion (Eggers et al.; paragraphs [0034] [0051] [0057] [0070] see “multi-step”).

As per claim 11, Eggers et al. disclose a medication management system for downloading a drug library from a medication management unit to a medical device having a primary memory and an existing drug library stored in the primary memory (Eggers et al.; paragraphs [0034] [0056] [0057]), comprising: a medication management unit having a processing unit and a storage medium coupled to the processing unit, the storage medium containing programming code executed by the processing unit (Eggers et al.; paragraph [0056] *see PDA) to: determine that a drug library update needed event has occurred (Eggers et al.; paragraphs [0034] [0056] [0057] *see location specific configuration), and transmit a new drug library from the medication management unit to a medical device upon occurrence of the drug library update needed event

(Eggers et al.; paragraphs [0036] [0057] [0058]); and a medical device in electronic communication with the medication management unit, having a processor and a primary memory coupled to the processor, the primary memory containing an existing drug library and programming code executed by the processor (Eggers et al.; paragraphs [0034] [0057] *see medical device) to: store the new drug library in a memory of the medical device while maintaining the existing drug library in the primary memory (Eggers et al.; paragraphs [0057] [0070]), determine that a specific trigger event has occurred (Eggers et al.; paragraphs [0034] [0057]), and replace the existing drug library in the primary memory with the new drug library upon occurrence of the trigger event (Eggers; paragraphs [0034] [0057]).

While Eggers et al. disclose storing the configuration and associated drug libraries in the memory of the infusion pump, Eggers et al. fail to specify storage in a cache memory. However, Examiner submits that it would have been obvious to use of the cache memory to store the drug library prior to storage in the bulk memory with the motivation of employing a well-known computer memory structure to facilitate a transfer of data.

As per claim 12, Eggers et al. disclose a system wherein the trigger event is selected from the group consisting of a completed infusion, a stopped infusion, a determination that the device is in a configurable mode, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs

[0034] [0057] [0063] see change configuration by location, patient, or updated library – NOTE:

The selection of additional trigger events to constitute a user choice that is accommodated by the Eggers disclosure).

As per claim 14, Eggers et al. disclose a system wherein the drug library update needed event is selected from the group consisting of a completed infusion, a stopped infusion, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library – NOTE: The selection of additional trigger events to constitute a user choice that is accommodated by the Eggers disclosure).

As per claim 15, Eggers et al. disclose a system wherein the medical device is adapted to perform an infusion using the existing drug library while the new drug library is transmitted (Eggers et al.; paragraphs [0034] [0057] [0070]).

As per claim 16, Eggers et al. disclose a system wherein the new drug library is stored in the memory while the medical device is performing an infusion (Eggers et al.; paragraphs [0034] [0057] [0070]).

Regarding claims 12 and 14-16, the obviousness and motivation as discussed with regard to claim 11 above are applicable to claims 12 and 14-16 and are herein incorporated by reference.

As per (newly added) claim 17, Eggers et al. disclose replacing an existing drug library (Eggers et al.; paragraphs [0066]-[0068]). Eggers et al. fail to specifically disclose deleting the old library. However, Examiner considers the decision to delete a library to constitute a user choice accommodated by the Eggers et al. system.

As per (newly added) claim 18, Eggers et al. disclose a system further comprising a master drug library needed to configure a plurality of types of medical devices including device and configuration identifiers (Eggers et al.; paragraphs [0034]-[0036] [0058] and [0066]-[0068] [0071]*see serial numbers, configuration ID, master database, and instructions to other med. devices).

As per (newly added) claim 19, Eggers et al. disclose a method wherein prior to being transmitted from the medication management unit to the medical device, entries into the new drug library are automatically pre-validated in real time as the entries are input into the new drug library by a rule set editor associated with the medication management unit (Eggers et al.; paragraphs [0063]-[0064] *see complete definitions and configurations prior to release).

As per (newly added) claim 20, Eggers et al. disclose notices including a new drug library download and a download successful (Eggers et al.; paragraphs [0066]-[0067] *see prompts concerning status of the library).

Regarding claims 17-20, the statements of obviousness and motivation to combine as discussed with regard to claims 1 and 11 above are applicable to claims 17-20 and are herein incorporated by reference.

[3] Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. in view of Examiner's Official Notice.

As per claim 3 and 13, Examiner enters the teachings of Eggers et al. in support of Examiner's Official Notice. Upon further review of the Eggers et al. disclosure it is clear Eggers et al. considers device use states or operational modes as a trigger event for a configuration update or retrieval (Eggers et al.; paragraphs [0066]-[0068] *see "power on").

While Eggers et al. fails to explicitly state that sleep and power-off modes as utilized as the trigger events, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the "power on" trigger disclosed by Eggers et al. with well known alternative equipment modes with the motivation of installing the appropriate configuration data prior to initiating an infusion (Eggers et al.; paragraphs [0066]-[0068]).

Response to Remarks

Applicant's remarks filed 2 January 2009 have been fully considered but they are not persuasive.

The remarks will be addressed below in the order in which they appear in the noted response.

Applicant remarks that Eggers et al. fail to render obvious the process defined by claim 1 of present application.

Specifically, Applicant remarks:

"Examiner admits, there is no suggestion [in Eggers et al.] that an existing configuration database is left in the primary memory of the medical device while a new configuration database is transmitted to a cache memory within the device and held in waiting in the cache memory of the medical device until a trigger event"

In response, Examiner initially notes that Eggers et al. fail to explicitly recite the use of cache memory to store configuration data prior to inputting the configuration data into the primary memory.

However, as correctly noted by Applicant, Eggers et al. disclose continual updating and exchanging of configuration data from configuration databases as well as the primary memory of

the device (Eggers et al.; paragraphs [0034] [0036] [0055] [0066] [0067]). Further, as also noted by Applicant, Eggers et al. disclose storing the configuration databases in various forms of memory. Eggers et al. further disclose exchanging or updating the configuration data through retrieval of a specific data sets identified by an ID number (Eggers et al.; paragraphs [0034]-[0037] [0055] [0064] [0066]). Accordingly, Eggers et al. maintains numerous configuration databases which are updated, retrieved from a number of memory sources and stored in the medical device based on the specific application or operating environment (i.e., trigger events).

Examiner maintains that Eggers et al. stores configuration databases in a memory and selectively retrieves the configuration data to update or replace a configuration database in the primary memory of the device. Eggers et al. does not indicate the deletion or removal of a configuration database from the source memory upon storing the database to the device for use.

While Eggers et al. fail to specify cache memory in this application, Examiner maintains that Eggers use of multiple memories to facilitate the storage and transfer of configuration data for use presents the same structure and function claimed by Applicant. Examiner further maintains that cache memory is well known in the art (as acknowledged by Applicant) and would have presented an obvious design choice in view of the noted teachings of Eggers et al.

Applicant additionally remarks:

"Eggers et al. fail to disclose that a power-on sleep mode or a power-off mode is used as a triggering event to replace the drug library..."

With respect to the updating of the configuration data in response to a trigger event, as noted by Applicant, Eggers et al. disclose a number of trigger events including location of the device, power up, and user input which prompt the retrieval of a specific configuration database (Eggers et al.; paragraphs [0066]-[0068]). Examiner maintains that these all constitute "trigger events" at least insofar as presently claimed by Applicant.

With respect to specific device modes of sleep and power-off modes serving as the "trigger events", Eggers et al. disclose that power up of the device could serve as a trigger for updating or retrieving a specific configuration database. Accordingly, Examiner submits that Eggers et al. clearly contemplate specific operational modes of the device as triggering an update. In view of this teaching by Eggers et al. Examiner maintains that the designation of other well known device operational modes (including sleep and power-off) to serve as the trigger event constitute an obvious design choice.

In conclusion, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 2 January 2009 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Engleson et al. and Eggers et al., based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the

remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (1 July 2008), and incorporated herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David RINES whose telephone number is (571) 272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JERRY O'CONNOR can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/R. D. R./
Examiner, Art Unit 3686
April 13, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686